Pharmacy Medical Necessity Guidelines:
Attention Deficit Hyperactivity Disorder Medications

Effective: August 1, 2017

<table>
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<th>Prior Authorization Required</th>
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This pharmacy medical necessity guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Step Therapy Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

**Adderall XR**
Adderall XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of Adderall XR in the treatment of ADHD was established on the basis of two controlled trials in children aged 6 to 12, one controlled trial in adolescents aged 13 to 17, and one controlled trial in adults who met DSM-IV criteria for ADHD.

**Adzenys XR-ODT™**
Adzenys XR-ODT is a central nervous system stimulant indicated for the treatment of ADHD in patients 6 years and older.

**Concerta®**
Concerta is indicated for the treatment of ADHD in children 6 years of age and older, adolescents, and adults up to the age of 65.

**Daytrana®**
Daytrana is indicated for the treatment of ADHD.

The efficacy of Daytrana in patients diagnosed with ADHD was established in two 7-week controlled clinical trials in children aged 6 to 12 and one 7-week, controlled clinical trial in adolescents aged 13 to 17.

**Dyanavel XR™**
Dyanavel XR is a central nervous system stimulant indicated for the treatment of ADHD.

**Focalin XR®**
Focalin XR is indicated for the treatment of ADHD in patients aged 6 years and older.

The effectiveness of Focalin XR in the treatment of ADHD in patients aged 6 years and older was established in two placebo-controlled studies in patients meeting DSM-IV criteria for ADHD.

**Metadate CD®**
Metadate CD is indicated for the treatment of ADHD.

The efficacy of Metadate CD in the treatment of ADHD was established in one controlled trial of children aged 6 to 15 who met DSM-IV criteria for ADHD.

**Procentra®**
Procentra is indicated for the treatment of ADHD in patients aged 3 to 16.

**Quillivant XR™**
Quillivant XR is indicated for the treatment of ADHD.
The efficacy of QUILLIVANT XR was established in a 2-week, placebo-controlled, laboratory classroom, crossover study in children aged 6-12 years with a diagnosis of ADHD. Patients in the trial met DSM-IV-TR® criteria for ADHD. Accumulated efficacy data from other methylphenidate products were also considered.

Ritalin® and Ritalin SR®
Ritalin® and Ritalin SR® are indicated for the treatment of ADHD in patients aged 6 years and older.

Ritalin LA®
Ritalin LA is indicated for the treatment of ADHD.

The efficacy of Ritalin LA in the treatment of ADHD was established in one controlled trial of children aged 6 to 12 who met DSM-IV criteria for ADHD.

Vyvanse®
Vyvanse is a central nervous system (CNS) stimulant indicated for the treatment of ADHD and for moderate to severe binge eating disorder in adults.

The efficacy of Vyvanse was established in three short-term trials in children aged 6 to 12, one short-term trial in children aged 13 to 17 and two short-term and one maintenance trial in adults.

Special Diagnostic Considerations
Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the patient and not solely on the presence of the required number of DSM-IV characteristics.

Need for Comprehensive Treatment Program
Drug treatment is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, and social) for patients with this syndrome. Drug treatment may not be indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician’s assessment of the chronicity and severity of the child’s symptoms.

COVERAGE GUIDELINES
Note: Prescriptions that meet the initial step therapy requirements will adjudicate automatically at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Tufts Health Plan Large Group Plans</th>
<th>Tufts Health Plan Small Group and Individual Plans</th>
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<td>Drug</td>
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<td>Tufts Health Plan Small Group and Individual Plans</td>
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<tr>
<td>methylphenidate SR (generic: Concerta)</td>
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### Step-2

- **Daytrana**
- **Dyanavel XR**
- **Quillivant XR**
- **Vyvanse**
- **Procentra**
- **Adderall**
- **Adderall XR**
- **Concerta**
- **Focalin XR**
- **Metadate CD**
- **Methylin Oral Solution**
- **Ritalin**
- **Ritalin LA**
- **Ritalin SR**

**Automated Step Therapy Coverage Criteria**

The following stepped approach applies to coverage of the Step-2 medications by the plan:

**Step 1**: Medications on Step-1 are covered without prior authorization for Members under the age of 25 years.

**Step 2**: The plan may cover medications on Step-2 for Members under the age of 25 years if the following criteria are met:

- The Member has had a trial of one (1) Step-1 or Step-2 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan.

**Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale**

The following stepped approach applies to ADHD medications covered by the plan:

**Step 2**: The plan may cover Step-2 medications for Members under the age of 25 years if the following criteria are met:

1. The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples.
Note: The plan may cover medications on Step-2 if a Member has received one of the non-covered medications, listed below under the limitations section, as evidenced by physician documented use, excluding the use of samples.

Coverage criteria for Members 25 years and older
In addition to the stepped approach that applies to ADHD medications, the plan may cover ADHD medications for Members 25 years and older if the following criteria are met:
1. Documented diagnosis of one of the following:
   - Narcolepsy
   - ADHD before the age of 12 years
   - Depressive condition in which the stimulant will be used as an augmenting agent with concomitant antidepressant medication(s)
   - Traumatic brain injury
   OR
2. Documentation by the provider there was evidence of signs or symptoms of ADHD before the age of 18 years
   OR
3. The Member has documented excessive daytime sleepiness associated with a documented diagnosis of one of the following chronic medical conditions:
   - Depression
   - Chronic Fatigue Syndrome
   - Multiple Sclerosis
   - Organic Brain Disorder
   - Obstructive Sleep Apnea/Hypopnea Syndrome
   - Parkinson’s Disease

Note: The plan recommends the Provider reviews Member-specific medication usage through the state(s) Online Prescription Monitoring Program.

Vyvanse (lisdexamphetamine)
Vyvanse (lisdexamphetamine) may be covered for Binge Eating Disorder (B.E.D.) if ALL of the following criteria are met and a PA request to Tufts Health Plan using the Universal Pharmacy Medical Review Request Form is submitted:
1. Documented diagnosis of Binge Eating disorder (B.E.D.)
   AND
2. The Member is at least 18 years of age

Note: The provider attests that the information provided, for any request above, is accurate and true, and that documentation supporting this information is available for review if requested by the plan.

LIMITATIONS
1. Medications on Step-2 are not covered unless the above step therapy criteria are met.
2. Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
3. The plan does not cover the following medications on all Commercial formularies: Adzenys XR-ODT, Aptensio XR, Desoxyn, Evekeo, Focalin, Quillichew ER, or Zentedi. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.
4. The plan does not cover the following medications, in addition to those noted in limitation #3, on the small group and individual formularies or the Tufts Health Direct formulary: Adderall, Adderall XR, Concerta, Focalin XR, Metadate CD, Methylin Oral Solution, Ritalin, Ritalin LA, Ritalin SR and Procentra.

CODES
None

REFERENCES
7. Daytrana (methylphenidate) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; 2015 April.
10. Focalin XR (dextmethylphenidate) [prescribing information]. East Hanover, NJ.: Novartis. 2013 December.
18. Quillichew ER (methylphenidate) [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc; Dec 2015.
22. Zenzedi (dextroamphetamine) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals LLC; May 2015.

**APPROVAL HISTORY**

April 11, 2006: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- July 11, 2006: Changed topic from “Focalin™ XR (dextmethylphenidate extended-release) Capsules” to “Medications for the Treatment of ADHD”. Added “or Daytrana (methylphenidate transdermal patch)” to clinical coverage criteria. Added “Methylphenidate ER” to formulary agents under coverage criteria
- July 10, 2007: No changes
- July 8, 2008: Added Vyvanse (lisdexamfetamine dimesylate) to pharmacy medical necessity guidelines. Added automated step therapy coverage guidelines for the Tufts Health Plan Commercial and Generic Focused Formulary. Added limitation that medications on Step-2 are not covered unless the above step therapy criteria are met.
- September 9, 2008: Updated step therapy criteria for coverage of a Step-2 medication from a 30-day trial of two (2) Step-1 ADHD medications OR one (1) Step-1 and one (1) Step-2 ADHD medication OR two (2) Step-2 ADHD medications to a 30-day trial of two (2) Step-1 ADHD medications OR a previous paid claim of a Step-2 ADHD medication. Added Liquadd™ (dextroamphetamine oral solution) to Step-2 of the pharmacy medical necessity guidelines.
- July 14, 2009: Added dextroamphetamine/amphetamine SR to list of Step-1 drugs. Moved Adderall XR to non-covered status for the Generic Focused Formulary (GFF)
• September 8, 2009: Added Procentra (dextroamphetamine oral solution) to Step-2 of the pharmacy medical necessity guidelines
• November 10, 2009: Removed Liquadd (dextroamphetamine oral solution) from guidelines, drug has been discontinued. Effective 1/1/2010, for Tufts Health Plan Medicare Preferred formularies, moved ADHD drugs from prior authorization to automated step therapy prior authorization.
• January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
• July 13, 2010: Added methamphetamine HCl to Step-1 drugs
• September 14, 2010: Added Concerta, Metadate CD, and Ritalin LA to Step-2. Moved Adderall XR, Adderall, Desoxyn, Dexedrine Spansules, Focalin, Metadate ER, Ritalin and Ritalin SR to not covered (Step-3) and added criteria for coverage. Changed Step-2 criteria to requiring a 30-day trial of one (1) Step-1 medication. Added “or Step-3” as a prerequisite for step-2 drugs.
• January 11, 2011: Removed Dexedrine Spansules and Metadate ER 10 mg from Step Therapy criteria as they have been discontinued by the manufacturer.
• May 10, 2011: Added methylphenidate SR (generic Concerta) to Step-2 of the Medical Necessity Guidelines.
• July 12, 2011: Removed the Not Covered (Step 3) criteria. Added Adderall XR to Step-2 of the Medical Necessity Guideline due to the unavailability of the generic.
• September 9, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
• September 13, 2011: Moved methylphenidate SR (generic Concerta) to Step 1 of the Medical Necessity Guidelines.
• November 15, 2011: Added Adderall to Step-1 of the medical necessity guidelines as the generic is unavailable.
• January 10, 2012: Added methylphenidate ext-rel (generic Ritalin LA) to Step-1 of the medical necessity guidelines. Added Ritalin back on Step-2 of the Medical Necessity guidelines due to shortage of generic.
• May 8, 2012: Added Ritalin SR back to Step-2 of the Medical Necessity guidelines and moved Ritalin LA to not covered status for GFF due to generic launch.
• June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
• November 6, 2012: Removed Methylin ER, product has been discontinued. Added generic methylphenidate ext-rel (Metadate CD) to Step-1 of the Medical Necessity Guidelines and moved Metadate CD to not covered status for GFF. Added use of samples or vouchers/coupons for brand name medications limitation. Added Ritalin LA 10mg to Step-2 of Medical Necessity Guidelines for the GFF. Moved Adderall, Adderall XR, Concerta, Ritalin, Ritalin LA 20mg, 30mg, 40mg and Ritalin SR to not covered status for the GFF. Moved Adderall to Step-2 of Medical Necessity Guidelines.
• October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
• January 14, 2014: Added dexamethylphenidate ext-rel 15 mg and 30 mg and dextroamphetamine sulfate solution to Step 1. Moved Focalin XR and Procentra to Not covered for the GFF.
• April 1, 2014: Removed language pertaining to the Generic Focused Formulary and added the EHB MA/RI Formulary.
• July 8, 2014: Added the note Tufts Health Plan may cover medications on Step-2 if a member has received one of the following noncovered medications within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use for those not meeting the automated step therapy: Desoxyn, Focalin, or Zenzedi.
• March 10, 2015: Added Evekeo to the list of Non-covered drugs. Also, added criteria for Vyvanse for Binge Eating disorder.
• July 14, 2015: For effective date October 1, 2015: Updated step therapy to note that the step therapy applies to members under the age of 25 years. Added criteria for members 25 years and older.
• September 16, 2015: Effective 10/1/15: Added Aptensio XR to the list of non-covered drugs. Also, clarified the criteria for 25 and older requests require documentation of diagnosis.
November 10, 2015: Added the following note: The provider attests that the information provided, for any request above, is accurate and true, and that documentation supporting this information is available for review if requested by the health plan.

January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.

March 8, 2016: Effective March 14, 2016 – added the following criteria for members 25 and older: Documentation by the provider there was evidence of signs or symptoms of ADHD before the age of 18 years OR The member has documented excessive daytime sleepiness associated with a documented diagnosis of one of the following chronic medical conditions: Depression, Chronic Fatigue Syndrome, Multiple Sclerosis, Organic Brain Disorder, Obstructive Sleep Apnea/Hypopnea Syndrome, Parkinson’s Disease.

June 14, 2016: Added Dyanavel XR to the Step Therapy program. Added Adzenys XR-ODT to the list of non-covered drugs.

July 12, 2016: Added Quillichew ER to the list of non-covered drugs.

September 13, 2016: Removed the following language from “and bipolar disease, thyroid disease, cardiovascular conditions have been ruled out” from criterion #1 under Coverage Criteria for Members 25 Years of Age or Older for a documented diagnosis of a depressive condition in which the stimulant will be used as an augmenting agent with concomitant antidepressant medications.

November 15, 2016: Moved brand Methylin chewable tablets to Non-covered for Small Group and Individual formularies.


BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink™ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.